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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,328	12/16/2003	Satoru Kuhara	JG-YY-4946D-C/500569.	6127

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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8-4

Office Action Summary	Application No.	Applicant(s)	
	10/737,328	KUHARA ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/499,717.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: applicant indicates that cases 10/053,326 and 09/499,717 are parent cases of this instant case in the first sentence of the specification. However, it is unclear whether applicant claims priority for these parent cases in the first sentence of the specification or not; and (2) since the cases 10/053,326 and 09/499,717 have abandoned, applicant is required to update information for these cases in the first sentence of the specification

Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 14-18 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rehman *et al.,* (Nucleic Acids Research, 27, 649-655, January 1999) in view of Collins *et al.,* (US Patent No. 5,702,896, published on December 1997).

Regarding claims 14-18 and 22-24 , Rehman *et al.,* teach immobilization of acrylamide-modified oligonucleotides on a carrier by co-polymerization. Aliquots of gel solution (0.2 μl) containing 75% glycerol, 10% total acrylamide (29:1 w/w acrylamide:bis-acrylamide), 5 μM 5' acryl-amide oligonucleotide, 0.125% w/v APS and 0.125% v/v TEMED were manually pipetted onto silanized glass microscope slides (acrylic silane-treated slides; CEL Associates, Houston, TX). Spotted slides were placed in a humid nitrogen atmosphere at room temperature for 5 min to allow polymerization. Polymerized slide arrays were subjected to electrophoresis in an agarose minigel box (50 mM Tris-acetate, pH 7.8, 2 mM EDTA, 20 V/cm, 20 min) to remove non-immobilized probe. Slides were rinsed in TE buffer or water and dried with a stream of nitrogen as recited in claims 16 (see right column in page 650 and pages 653 and 654, and Figure 6). Hybridization of the slide and washing the slide were performed at room temperature (see page 651, left column). Note that: (1) the gel solution containing acrylamide (29:1 w/w acrylamide:bis-acrylamide), APS and TEMED is considered to contain a hydrophilic polymer (polyacrylamide) as recited in claim 14 since APS and TEMED in the gel solution gradually enhanced acrylamide:bis-acrylamide polymerization to form polyacrylamide as recited in claim 24 (containing at least some of polyacrylamide in the gel solution before complete polymerization); (2) since co-polymerization attachment is specific for the terminal acrylamide group of the oligonucleotides (see abstract in page 649, right column in page 651, and Figure 1), acrylamide-modified oligonucleotides is considered to be indirectly fixed to the slide at its one end portion (5' terminus) as recited in claim 15; (3) silanized glass

microscope slide is considered as a glass sheet as recited in claims 17 and 18; and (4) polyacrylamide is considered as a nonionic hydrophilic polymer as recited in claim 22 (see the specification, page 8, second paragraph) and a cellulose derivative as recited in claim 23 (containing carbon atoms).

Regarding claim 21, 5' -amino oligonucleotide was used in the method recited in claim 1 (see right column in page 651).

Regarding claim 25, as shown above, APS and TEMED in the gel solution gradually enhanced acrylamide:bis-acrylamide polymerization to form polyacrylamide. Since polyacrylamide is a polymer of acrylamide and initial concentration of polyacrylamide is zero, although one having ordinary skill in the art at the time the invention was made does not know exact concentration of polyacrylamide in the gel solution at each time point before gel complete polymerization, 0.1 to 2% polyacrylamide in the gel solution can be reached at some point during the process of gel polymerization. Therefore, in the absence of convincing evidence to the contrary, the limitation as recited in claim 25 is considered to be inherent to the reference taught by Rehman *et al.*.

Rehman *et al.*, do not disclose to heat a solid support after a hybridization assay such as washing the slide at high temperature as recited in claims 14 and 16.

Collins *et al.*, teach to reduce non-specific binding in a hybridization assay by washing non-specific bound probes from a solid support at high temperature (see lines 53-67 in column 2 and lines 1-10 in column 3).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have heated the carrier after the steps of washing and drying the carrier as recited in claims 14 and 16 in view of the prior art of Rehman *et al.*, and

Collins *et al.*. One having ordinary skill in the art would have been motivated to do so because Collins *et al.*, have successfully reduced non-specific binding in a hybridization assay by washing non-specific bound probes from a solid support at high temperature (see lines 53-67 in column 2 and lines 1-10 in column 3) and the simple replacement of one well known washing procedure (i.e., washing at room temperature taught by Rehman *et al.*,) from another well known (i.e.,washing at high temperature taught by Collins *et al.*.,) during a hybridization assay would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because the replacement would reduce non-specific binding in a hybridization assay.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07, and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rehman *et al.*, (January 1999) in view of Collins *et al.*, (1997) as applied to claims 14-18 and 21-25 above, and further in view of Brown *et al.*, (US Patent No. 5,807,522, published on September 15, 1998). The teachings of Rehman *et al.*, and Collins *et al.*, have been summarized previously, *supra.*

Rehman *et al.*, and Collins *et al.*, does not disclose to spot nucleic acids onto a glass sheet (slide) pretreated with poly-L-lysine as recited in claim 19.

Brown *et al.,* do teach to spot nucleic acids onto a glass sheet pretreated with poly-L-lysine (see columns 16-18).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have spotted nucleic acids onto a glass sheet pretreated with poly-L-lysine in view of the prior art of Rehman *et al.,* Collins *et al.,* and Brown *et al.*. One having ordinary skill in the art would have been motivated to do so because: (1) immobilization of nucleic acids onto a glass sheet pretreated with poly-L-lysine was known in the art at the time the invention was made and the use of a solid support with a layer of positive charges would enhance efficiency of the immobilization of nucleic acid (with negative charges) on the sold support; and (2) the simple replacement of one kind of solid support (i.e.,glass slides without poly-L-lysine) from another kind of solid support (i.e.,glass slides pretreated with poly-L-lysine) in a method of fixing nucleic acid to a solid carrier would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rehman *et al.*, (January 1999) in view of Collins *et al.*, (1997) as applied to claims 14-18 and 21-25 above, and further in view of Shi et al., (US Patent No. 5,919,626, published on July 6, 1999).

The teachings of Rehman *et al.*, and Collins *et al.*, have been summarized previously, *supra.*

Rehman *et al.*, and Collins *et al.*, do not disclose to spot nucleic acids onto a glass sheet (slide) pretreated with a silane coupling agent having an epoxy group as recited in claim 20.

Shi *et al.*, do teach to spot nucleic acids onto a glass sheet pretreated with a silane coupling agent having an epoxy group (see columns 8, 14, 15, and 22).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have spotted nucleic acids onto a glass sheet pretreated with a silane coupling agent having an epoxy group in view of the prior art of Rehman *et al.*, Collins *et al.*, and Shi *et al.*. One having ordinary skill in the art would have been motivated to do so because immobilization of nucleic acids onto a glass sheet pretreated with a silane coupling agent having an epoxy group was known in the art at the time the invention was made and the simple replacement of one kind of solid support (i.e., acrylic silane-treated glass slides) from another kind of solid support (i.e., glass slides pretreated with a silane coupling agent having an epoxy group) in a method of fixing nucleic acid to a solid carrier would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their

expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Conclusion

6. No claim is allowed.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703)872-9306 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
June 10, 2004

FRANK LU
PATENT EXAMINER